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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/147,914 05/25/99 EYAL

A U-012130-1

EXAMINER

HM12/0828

LADAS & PARRY
26 WEST 61ST STREET
NEW YORK NY 10023

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ART UNIT

PAPER NUMBER

1623
DATE MAILED:

08/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/147,914

Applicant(s)

Eyal et al

Examiner

Oh Taylor Victor

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 11, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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Non-Final Rejection

1. The rejection of claims 1 and 34 under 35 U.S.C. 112, second paragraph is withdrawn due to the correction made in the amendment .
2. Applicant's arguments with respect to claims 1-35 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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3. Claims 1-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Voelskow et al (US 4,467,034) in view of Hammond (WO 95/32301) and Walkup et al (US 5,252,473).

Voelskow et al disclose a process for the production of lactic acid from the fermentation of lactose and its purification by means of ion exchange (see page 2 , lines 1-2) in the following steps:

- a. converting a fermented solution to a sodium lactate solution by the addition of NaOH to a pH of 6.5 to 6.8,
- b. subjecting the aqueous stream containing from 5 to 7% of sodium lactate to ion exchangers (see col. 5, lines 7-8),
- c. adsorbing the lactic acid on the column and subsequently isolating the resulting lactic acid product with the elution of hydrochloric acid (see columns 5 and 6. Example 5),

However, the instant invention differs from Voelskow et al in the followings: a cation and anion exchanger are liquid exchangers, the hydrolysis is conducted at a temperature higher than 80° C. in a CO₂ containing atmosphere, the second product is used as a neutralizing agent in fermentation, and the recovery of the lactic acid is made by the use of the distillation.

Hammond teaches a method of preparing an organic acid or its salt by passing the acidic solution withdrawn from the bioreactor through a column of an anion exchanger regenerated with alkali metal hydroxide to recover an acid as an alkali salt ; furthermore, the acid can be obtained from passing the alkali metal solution salt through a column of cation exchanger in hydrogen ion form (see page 1, lines 15-24).

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Furthermore, Walkup et al disclose a process of producing lactic acid and esters of lactic acid in the following reactions. In the first reaction, ammonium lactate produced by a fermentation process of carbohydrate materials (see col. 3 , lines 37-40) can be decomposed into NH_3 , which can be used for controlling pH in the fermentation (see col. 2, lines 6-8) and lactic acid (see col. 6 , line 5) ; furthermore, purified lactic acid can be produced from the CO_2 catalysis of ammonium lactate and alcohol solution in the presence of an acid ion exchange resin at a temperature in the range of 100° to 150° C. (see col.14 , lines 26-40). In addition, a simple distillation is recommended to purify the desired product (see col.14 , lines 53-57).

Concerning the use of the liquid cation and anion exchangers, the references are silent. However, there is little difference between the use of the solid and liquid ion exchangers and they are well-known in the art. Therefore, it would have been obvious for the skillful artisan to have used the liquid ion exchangers as an alternative to the solid ion exchangers with an expectation of a similar success.

Therefore, if person having an ordinary skill in the art had wished to develop the purification process of lactic acid involved in the hydrolysis in the presence of the CO_2 containing atmosphere by the use of the distillation, it would have been obvious for the skillful artisan to have used Hammond's anion exchanger followed by Voelskow et al's cation exchanger , along with Walkup et al's hydrolysis and distillation in order to increase the efficiency of the overall process.

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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Eyal et al (U.S. 5,766,439) discloses a process for producing an organic acid in the following steps : producing an organic acid by fermentation, adding an alkaline earth base to the fermentation, reacting the alkaline earth salt of the organic acid with a source of ammonium ions, reducing the concentrations of divalent cations, and converting the ammonium of the organic acid to free organic acid.

Sterzel et al (U.S. 5,453,365) discloses a preparation of lactates by fermentation of the mixture of sugars, conversion of the lactic acid followed by esterification during the process, in which the lactic acid is neutralized with an alkaline earth metal carbonate, added with ammonia and carbon dioxide, and the purified ammonium lactate solution is esterified with an alcohol.

Urbas (U.S. 4,444,881) discloses a process for the recovery of organic acids from dilute aqueous solutions in the following steps: adding a water-soluble tertiary amine carbonate to the calcium salt solution to form the trialkylammonium salt of the acid, and heating the concentrated trialkylammonium salt solution to obtain the acid and the amine.

Cockrem et al (U.S. 5,210,296) discloses a process for producing a high pure lactate ester or lactic acid from a concentrated fermentation broth by acidification in the presence of an alcohol with sequential esterification, distillation of high purity ester.

Kumagai et al (EP 0614983A2) discloses a method of producing lactic acid and lactic esters in the following steps : carrying out the adjustment of the pH of a culture medium

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containing lactic acid with ammonia, adding an alcohol, a mineral to the solution so as to undergo the esterification process.

Baniel et al (U.S. 5,510,526) discloses a process for the recovery of lactic acid from a lactate solution from a fermentation broth in the presence of a basic substance such as ammonium hydroxides by way of extraction or ammonium salt formation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. Victor Oh whose telephone number is (703) 305-0809. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist, can be reached on (703) 308-1701. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

CV
8/27/01


PAUL J. KILLOS
PRIMARY EXAMINER
A.U. 1623